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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,174	10/29/2003	Swaminathan Jayaraman	795-A03-004	7393

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,174	JAYARAMAN, SWAMINATHAN	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 70,72,74-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et. (6524795) in view of Wolff et al. (WO 91/12779). Francis et al. disclose a method of examining walls of a patient for restenosis (which inherently is proliferation of smooth muscle cells having a spindle shape, see Kunz et al. 5733925), col. 8, lines 39-41, col. 13, lines 35-57, col. 58, lines 61-67. Francis et al. also disclose to provide a treatment with the patient having the vascular disease and this can include using a drug covered stent, col. 25, lines 5-9. However, Francis et al. do not explicitly disclose the stent covered is a plurality of stent performs with a metallic core encapsulated with caps and a combination of therapeutic agents. Wolff shows (Figs. 1,17) a plurality of stent performs **12** to form a stent **10**. Fig. 4 shows a stent perform with a metallic core **22** and an outer sheath **14** disposed about the contact surface. It can be seen (Figs. 12,15,17) that end caps exist on the core to encapsulate the ends of the wire. Wolff discloses the sheath on the metallic core can include a therapeutic agent, page 10, lines 35,36. Wolff et al. also disclose that the sheath is a polymer and can be bioabsorbable, page 12, lines 16-18. It is inherent there is pores in the sheath or coating since it allows for elution of the drug, page 10, lines 36-38. Additionally, Wolff discloses two therapeutic agents could be used, page 15, lines 19,20. It would have

been obvious to one of ordinary skill in the art to use the restenosis stent of Wolff et al. with the method of treating a patient by Francis et al. such that it provides a flexible stent and enables the patient to receive multiple treatment materials to the patient having a restenosis condition.

Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et. '795 in view of Wolff et al. (WO 91/12779) as applied to claim 70 above, and further in view of Kahan et al. (Transplantation, 1991 per Applicant's IDS). Wolff does disclose the therapeutic agents can be cell inhibiting, page 9. However, Francis as modified by Wolff fail to explicitly disclose the combination of drugs include rapamycin and cyclosporine. Kahan et al. teach that a combination of the drugs rapamycin and cyclosporine provide a synergistic effect, see abstract. It would have been obvious to one of ordinary skill in the art to utilize the combination of drugs of rapamycin and cyclosporine as taught by Kahan et al. with the stent of Francis as modified by Wolff et al. such that it enhances the immunosuppression of the smooth muscle cells involved in restenosis.

Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et. '795 in view of Wolff et al. (WO 91/12779) as applied to claim 70 above, and further in view of Liprie et al. (6491662). Wolff does disclose the stent can be made from self-expanding material, page 10, line 27. However, Francis as modified by Wolff fail to explicitly disclose the core stent material is made of shape memory alloy. Liprie et al. teach that a core is made of shape memory alloy to strengthen the vascular device, col. 2, lines 36-43. It would have been obvious to one of ordinary skill in the art to substitute

metal materials and use a SMA as taught by Liprie with the stent of Francis as modified by Wolff et al. such that it is flexible enough for delivery through a tortuous vessel, but stiff enough to not crimp.

Claims 78,79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et. '795 in view of Wolff et al. (WO 91/12779) as applied to claim 70 above, and further in view of Barclay et al. (2002/77693). Francis et al. in view of Wolff et al. is explained supra. Wolff et al. does disclose multiple polymer layers can be used, Fig. 3B and page 15, lines 11-21. However, Francis et al. as modified by Wolff et al. fail to disclose the drug is coated over the sheath and also using a release layer. Barclay et al. teach (Fig. 5E) a stent **139** can have an outer sheath **141A** and then a drug layer **147** and then a release layer **143**. This enables the drug to be delivered to the lumen tissue and not the blood. It would have been obvious to place the drug layer on a sheath layer and then a release layer of polymer on the stent as taught by Barclay et al. with the stent of Francis modified with the stent filaments of Wolff et al. such that it can treat the lumen.

Response to Arguments

Applicant's arguments with respect to claim 70 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's argument that the Wolff reference fails to show certain features of applicant's invention, it is noted that

the features upon which applicant relies (i.e., core completely encapsulated) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). According to Figs. 1,12,15,17 of Wolff, the ends must be encapsulated otherwise it would be showing the core as illustrated in an embodiment that does not encapsulate the ends, see Fig. 13. Wolff can be said to meet the claim limitations regarding the stent structure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738